OCT - 7 2003

510(K) SUMMARY

K031909

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. Submitter's Name: **BeTeC Medical Science Co., Ltd.**
   Address: 55 Tower, No. 84/53, 84 Sukhumvit 55, Prakanong, Bangkok, Thailand 10110.
   Phone: 66-2-3810781
   Fax: 66-2-3810780
   Contact: Mr. Ching Chao Hou, Director

2. Device Name :
   Trade Name: BeTeC Retractable Safety Syringe (5ml)
   Common Name: Safety Syringe (with or without needle)
   Classification name: Anti-Stick Syringe/ Piston Syringe
   Single lumen Hypodermic Needle

3. Classification: Class II
   Regulatory Number: 880.5860 & 880.5570

4. Predicate Device:
   - **TMD™ Safety Syringe (FA13 Series 5ml)with 510K number K022278**
     Marketed by Taiject Medical Device Co., Ltd.

5. Device Description:
   BeTeC Retractable Safety Syringe
   The ***BeTeC Retractable Safety Syringe*** is sterile, single-use, disposable , Non-reusable, Manual , Retractable, 5ml Piston Syringe, provided with or without needle, which is used for injection of fluids into or withdraw from the body. (Only use needle $1^{1/2}$" or shorter, 21-28 gauge)

   The *BeTeC Retractable Safety Syringe* consists of the following major components :barrel, plunger, plunger ring, nozzle, nozzle ring, needle cap, needle + needle hub.

6. Intended Use:
   The *BeTeC Retractable Safety Syringe* is designed as an anti-stick syringe to aid in the prevention of sharps injuries and the potential for syringe reuse and is a single use, disposable and manual retractable safety syringe which is intended for injection of medical fluids into or withdraw from the body.

7. Performance Summary:	In terms of Physical specification, Chemical specification, Biological specification & Sterilization Specification, the device conforms to applicable standards included ISO 7864, ISO 7886-1, ISO 10993 series, ISO 11607-1, ISO 11135, USP Pyrogenic standards & related standards----etc.

8. Conclusions:

The **BeTeC Retractable Safety Syringe** has the same intended use and similar technological characteristics as the **TMD™ Safety Syringe --FA13 Series 5ml** markdet by **Taiject Medical Device Co., Ltd.** Moreover, bench testing contained in this submission and clinical testing supplied demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **BeTeC Retractable Safety Syringe** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 7 2003

Harvest Consulting Company
C/O Ms. Jennifer Reich
Betec Medical Science Company, Incorporated
3892 South America West Trail
Flaggstaff, Arizona 86001

Re: K031909
Trade/Device Name: BeTeC Retractable Safety Syringe (5ml)
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: September 12, 2003
Received: September 17, 2003

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

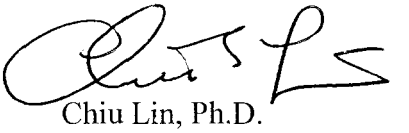
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): *K031909*

DEVICE NAME: BeTeC Retractable Safety Syringe
BeTeC Medical Science Co., Ltd.

INDICATIONS FOR USE:

The **BeTeC Retractable Safety Syringe (5ml)** is designed as an anti-stick syringe to aid in the prevention of sharps injuries and the potential for syringe reuse and is a single use, disposable and manual retractable safety syringe which is intended for injection of medical fluids into or withdraw from the body.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR Over-The-Counter _____
(Per 21 CFR 801.109)

Patricia Cucente
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031909